Hearing Date and Time: April 22, 2020, at 10:00 a.m. (prevailing Eastern Time)
Objection Date and Time: April 15, 2020, at 4:00 p.m. (prevailing Eastern Time)

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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (RDD)**
Debtors.[1]	**(Jointly Administered)**

NOTICE OF HEARING ON MOTION OF DEBTORS FOR AUTHORIZATION TO ENTER INTO FUNDING AGREEMENT

PLEASE TAKE NOTICE that on April 1, 2020, the above-captioned debtors and debtors in possession in these proceedings (collectively, the "**Debtors**") filed the *Motion of Debtors for Authorization to Enter into Funding Agreement* (the "**Motion**"). A hearing on the Motion will be held on **April 22, 2020 at 10:00 a.m.** (prevailing Eastern Time) (the "**Hearing**")

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

before the Honorable Robert D. Drain, United States Bankruptcy Judge, United States Bankruptcy Court for the Southern District of New York, at the United States Bankruptcy Court for the Southern District of New York, 300 Quarropas Street, White Plains, New York 10601 (the "**Bankruptcy Court**"), or at such other time as the Bankruptcy Court may determine; *provided* that, pursuant to General Order M-543, dated March 20, 2020 (Morris, C.J.) ("**General Order M-543**"), such Hearing shall be conducted telephonically so long as General Order M-543 is in effect or unless otherwise ordered by the Bankruptcy Court.[2]

PLEASE TAKE FURTHER NOTICE that the Hearing may be continued or adjourned thereafter from time to time without further notice other than an announcement of the adjourned date or dates at the Hearing or a later hearing. The Debtors will file an agenda before the Hearing, which may modify or supplement the motions to be heard at the Hearing.

PLEASE TAKE FURTHER NOTICE that any responses or objections (the "**Objections**") to the Motion shall be in writing, shall conform to the Federal Rules of Bankruptcy Procedure and the Local Bankruptcy Rules for the Southern District of New York, shall be filed with the Bankruptcy Court (a) by attorneys practicing in the Bankruptcy Court, including attorneys admitted *pro hac vice*, electronically in accordance with General Order M-399 (which can be found at www.nysb.uscourts.gov), and (b) by all other parties in interest, on a CD-ROM, in text-searchable portable document format (PDF) (with a hard copy delivered directly to Chambers), in accordance with the customary practices of the Bankruptcy Court and General Order M-399, to the extent applicable, and shall be served in accordance with the *Second Amended Order Establishing Certain Notice, Case Management, and Administrative*

[2] A copy of General Order M-543 can be obtained by visiting http://www.nysb.uscourts.gov/news/court-operations-under-exigent-circumstances-created-covid-19.

Procedures entered on November 18, 2019 [ECF No. 498], so as to be filed and received no later than **April 15, 2020** at **4:00 p.m.** (prevailing Eastern Time) (the "**Objection Deadline**").

PLEASE TAKE FURTHER NOTICE that parties wishing to appear for, attend or participate in the Hearing must make arrangements through CourtCall by telephone at 1-888-882-6878.

PLEASE TAKE FURTHER NOTICE that any objecting parties are required to attend the Hearing and a failure to appear may result in relief being granted upon default; *provided* that objecting parties shall attend the Hearing **telephonically** so long as General Order M-543 is in effect or unless otherwise ordered by the Bankruptcy Court.

PLEASE TAKE FURTHER NOTICE that if no Objections are timely filed and served with respect to the Motion, the Debtors may, on or after the Objection Deadline, submit to the Bankruptcy Court an order substantially in the form of the proposed order annexed to the Motion, which order may be entered without further notice or opportunity to be heard.

PLEASE TAKE FURTHER NOTICE that copies of the Motion may be obtained free of charge by visiting the website of Prime Clerk LLC at https://restructuring.primeclerk.com/purduepharma. You may also obtain copies of any pleadings by visiting the Bankruptcy Court's website at http://www.nysb.uscourts.gov in accordance with the procedures and fees set forth therein.

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Dated: April 1, 2020
New York, New York

DAVIS POLK & WARDWELL LLP

By: */s/ Eli J. Vonnegut*

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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (RDD)**
Debtors.[1]	**(Jointly Administered)**

MOTION OF DEBTORS FOR AUTHORIZATION
TO ENTER INTO FUNDING AGREEMENT

Purdue Pharma L.P. ("**PPLP**") and its affiliates that are debtors and debtors in possession in these proceedings (collectively, the "**Debtors**") hereby file this *Motion of Debtors for Authorization to Enter into Funding Agreement* (the "**Motion**"). In support of this Motion, the Debtors respectfully state as follows:

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

Relief Requested

1. By this Motion (the "**Motion**"), and pursuant to sections 105(a) and 363(b) of the United States Code, 11 U.S.C. § 101, *et seq*. (as amended or modified, the "**Bankruptcy Code**"), the Debtors seek entry of an order, substantially in the form attached hereto as **Exhibit A** (the "**Order**"), authorizing the Debtors to enter into an agreement substantially in the form of the Funding Agreement (the "**Agreement**") attached hereto as **Exhibit B** with Harm Reduction Therapeutics, Inc. ("**HRT**").

Jurisdiction and Venue

2. The United States Bankruptcy Court for the Southern District of New York (the "**Court**") has jurisdiction to consider this matter pursuant to 28 U.S.C. §§ 157 and 1334 and the Amended Standing Order of Reference M-431, dated January 31, 2012 (Preska, C.J.). This is a core proceeding pursuant to 28 U.S.C. § 157(b)(2) and, pursuant to Rule 7008 of the Federal Rules of Bankruptcy Procedures (the "**Bankruptcy Rules**"), the Debtors consent to entry of a final order by the Court in connection with this Motion to the extent that it is later determined that the Court, absent consent of the parties, cannot enter a final order or judgment consistent with Article III of the United States Constitution.

3. Venue is proper before the Court pursuant to 28 U.S.C. §§ 1408 and 1409.

General Background

4. On September 15, 2019 (the "**Petition Date**"), the Debtors each commenced with this Court a voluntary case (collectively, the "**Chapter 11 Cases**") under chapter 11 of the Bankruptcy Code. The Debtors are authorized to operate their businesses and manage their properties as debtors in possession pursuant to sections 1107(a) and 1108 of the Bankruptcy Code. On September 27, 2019, the United States Trustee for the Southern District of New York

appointed the official committee of unsecured creditors (the "**Committee**"). No trustee or examiner has been appointed in these Chapter 11 Cases.

5. Additional information about the Debtors' businesses and the events leading up to the Petition Date can be found in the *Debtors' Informational Brief* filed on September 16, 2019 [ECF No. 17].

There Is an Urgent Need for Low-Cost Over-the-Counter Naloxone Rescue Drug Products

6. The Centers for Disease Control and Prevention estimates that, every day, 130 Americans die from opioid overdose.[2] More of these deaths could be prevented if individuals, families, first responders and communities had greater access to naloxone, an opioid antagonist medication that can counter the effects of an opioid overdose. In intranasal form, naloxone can be administered by the general public with limited-to-no training. The Food and Drug Administration (the "**FDA**") supports efforts to increase the availability of naloxone medications and has publicly expressed its belief that the improved access to safe, effective and easy-to-use naloxone rescue drug devices is critical to reducing opioid overdose-related deaths.[3]

7. Naloxone is currently available only by prescription. The lack of an over-the-counter ("**OTC**") product results in two fundamental barriers to increasing availability: cost and access. The cost of prescription naloxone medications is a significant impediment to wider distribution, especially in communities hardest hit by the opioid crisis.[4] In addition, OTC

[2] Centers for Disease Control and Prevention, Understanding the Epidemic, https://www.cdc.gov/drugoverdose/epidemic/index.html.

[3] *See* U.S. Food and Drug Admin., FDA Statement, Statement on Continued Efforts to Increase Availability of All Forms of Naloxone to Help Reduce Opioid Overdose Deaths (Sept. 20, 2019), https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose ("Naloxone is a critical tool for individuals, families, first responders and communities to help reduce opioid overdose deaths.").

[4] *See* Gupta R. et al. *The rising price of naloxone — risks to efforts to stem overdose deaths*, N. Engl. J. Med. 2016; 375:2213-2215, https://www.nejm.org/doi/full/10.1056/NEJMp1609578.

availability has the potential to dramatically improve access. Individuals are often unable or unwilling to go through the process of visiting a doctor and navigating their insurance coverage in order to obtain a prescription for naloxone that then must be filled by a pharmacist. Many (but not all) states have attempted to address this concern by either issuing statewide orders enabling the sale of naloxone without a prescription or authorizing jurisdictions to pass naloxone standing order laws.[5] However, even these measures are imperfect and impose barriers to access.[6] OTC naloxone, by contrast, would not involve doctors, pharmacists or insurance companies and would require minimal to no touch points (OTC products may be purchased online in many cases).

8. As a result of these barriers, naloxone is being dramatically underprescribed to the American public.[7] One recent study found that making an OTC naloxone product available could result in a "substantial increase" in the number of products distributed, potentially as high as 179%.[8] The study noted this finding was comparable to historical examples of OTC conversions, such as certain smoking cessation medications that experienced increases of up to 180% in the rate of product distribution following OTC conversion.[9]

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[5] SAFEProject, *State Naloxone Access Rules and Resources*, https://www.safeproject.us/naloxone-awareness-project/state-rules/.

[6] Murphy, Morgan, Jeng and Schackman, *Will converting naloxone to over-the-counter status increase pharmacy sales?*, Health Serv Res. 2019; 54:765

[7] *See* Lin, L., Brummett, C.M., Waljee, J.F. et al., Association of Opioid Overdose Risk Factors and Naloxone Prescribing in US Adults, J. Gen. Intern. Med. 35, 420–427 (2020), https://doi.org/10.1007/s11606-019-05423-7 (concluding with respect to naloxone prescriptions that, "overall prescribing remains minimal. Additional efforts are needed across health systems to increase naloxone prescribing for patients at risk for opioid overdose.").

[8] *See* Murphy et al., *supra* note 6, at 54:764–772.

[9] *Id*. at 767.

9. The FDA agrees. In fact, the FDA (in what it describes as an "unprecedented step") completed part of the application itself, specifically label development and comprehension studies, as an incentive for an applicant to bring an OTC naloxone product to market.[10]

10. Purdue is committed to its transformation into a public benefit corporation that will advance meaningful solutions to the opioid crisis and save lives. Breaking down the twin barriers to availability of life-saving naloxone medications in an easy-to-use intranasal form—cost and access—is a core component of this initiative.

HRT's Team Has a Strong Track Record of OTC Conversions

11. Purdue is facilitating HRT's development of a low-cost OTC naloxone nasal spray device (the "**Product**"). HRT is a nonprofit independent pharmaceutical company organized exclusively for charitable, religious, educational and scientific purposes. HRT was founded in 2017 with a mission to save lives by making the Product available over-the-counter at low cost.

12. HRT's management team has a long and successful history transitioning prescription medications to OTC. Members of the management team have helped develop OTC versions of products such as Nicorette®, Plan B®, Nasacort® Allergy, NicoDerm® CQ®, Prilosec OTC® and Allegra®, among others. Members of the team also have deep expertise in addiction research and substance abuse treatment.

HRT Is Well Positioned to Continue Developing the Product

13. The Debtors began supporting HRT in its development of an OTC naloxone nasal spray in 2018. In September 2018, PPLP made a $3.42 million unrestricted grant to HRT to support development. Purdue agreed to fund an additional $2.5 million for further development of the Product in November 2019. In return, HRT affirmed its commitment to manufacture

[10] *Id.*

millions of units of the Product so that such units can be donated free-of-charge or sold at Cost (as defined in the Agreement).

14. The funding and other support from Purdue has enabled HRT to make significant and encouraging progress in the Product's development. This progress includes, among other things, HRT's development of the intranasal naloxone delivery device, Product formulation, participation in a Pre-Investigational New Drug Meeting with the FDA, submission of the Product's name for the FDA's review, and establishment and identification of advisory boards and vendors. HRT has also begun Chemistry, Manufacturing, and Control ("**CMC**") and formulation work, commenced final biocompatibility and other studies, and begun to prepare the Product's New Drug Application ("**NDA**"). In practical terms, HRT is well positioned for final FDA review and approval of the Product by the end of 2021.

15. However, as anticipated, HRT requires additional funding to complete the Product's development and FDA approval phase. By this Motion, the Debtors seek authorization to enter into the Agreement to fund the continuation of HRT's development work with the goal of obtaining regulatory approval for the Product.

16. The Debtors believe that HRT is well positioned to partner with Purdue to complete development of the Product because HRT has:

- a strong and experienced leadership and scientific team;
- a history of effective collaboration with the Debtors' senior management and scientists;
- a known and established intranasal device;
- a proprietary preservative-free 3 mg naloxone formulation well suited to intranasal delivery;
- an identified contract manufacturer and sales and distribution vendor;

- established scientific and commercial advisory boards; and
- a strong position to obtain FDA fast-track designation for the Product.

The Agreement

17. The Agreement provides that the Debtors will fund $11.5 million[11] for HRT to continue Product development in 2020–21, with each advance subject to HRT meeting certain development milestones (the "**Milestones**"). The Milestones are:

- $2.5 million upon the start of Scale-Up Batch at an identified, well-established contract manufacturer (which indicates progress towards formulation development, establishing the Product's stability, and further clinical study);
- $4 million upon the start of Phase 1 Study First Patient In (when testing of the Product with patients begins); and
- $5 million upon the completion of Phase 1 Study's Clinical Study Report (which indicates that certain data that is critical to filing an NDA has been collected and provided in the report).

18. These Milestones are projected to be achieved by May 2020, August 2020 and December 2020, respectively, and payments are not due until shortly after the specified events occur. The Debtors and HRT expect that the Agreement will fully fund research and development for the Product, including all clinical studies, through the NDA filing, which is anticipated to be made in the beginning of 2021, based on current information. The Agreement further provides for the Debtors to continue to provide support and assistance in the Product's development. The Agreement further contemplates that, subject to FDA approval of the Product, PPLP will provide funds to HRT to enable HRT to manufacture up to approximately 14.6 million

[11] In view of the current COVID-19 pandemic, HRT has reviewed timelines and cost estimates to determine whether any adjustments are required. At present, the timelines and cost estimates remain accurate, but it is possible that an extended pandemic will eventually result in longer timelines and corresponding increases in production costs.

units of the Product through 2029 so that such units can be donated free-of-charge or sold at Cost.

19. The Debtors hope that millions of doses of the Product will be distributed to communities around the country at low or no cost and believe that the availability of the Product in the United States would save thousands of lives per year. However, under the terms of the Agreement, the Debtors have no obligation to conduct any commercialization activities or purchase any Product. The maximum total costs that the Debtors are obligated to incur under the Agreement are limited to $11.5 million in Milestone payments plus the costs of certain of the Debtors' employees providing assistance to HRT during the development process.

20. The negotiation of the terms of the Agreement was conducted at arm's length. The terms of the Agreement have been reviewed, and entry into the agreement approved, by the independent Special Committee of PPLP's Board of Directors.

Basis for Relief Requested

21. Bankruptcy Code section 363(b)(1) empowers the Court to authorize a debtor to "use, sell, or lease, other than in the ordinary course of business, property of the estate." Under applicable case law, in this and other circuits, if a debtor's proposed use of its assets pursuant to section 363(b) of the Bankruptcy Code represents a reasonable business judgment on the part of the debtor, such use should be approved. *See, e.g., In re MF Global Inc.*, 467 B.R. 726, 730 (Bankr. S.D.N.Y. 2012) ("Although not specified by section 363, the Second Circuit requires that transactions under section 363 be based on the sound business judgment of the debtor or trustee."); *Comm. of Equity Sec. Holders v. Lionel Corp. (In re Lionel Corp.),* 722 F.2d 1063, 1070 (2d Cir. 1983) ("The rule we adopt requires that a judge determining a § 363(b) application expressly find from the evidence presented before him at the hearing a good business reason to

grant such an application."); *Comm. of Asbestos-Related Litigants v. Johns-Manville Corp. (In re Johns-Manville Corp.)*, 60 B.R. 612, 616 (Bankr. S.D.N.Y. 1986) ("Where the debtor articulates a reasonable basis for its business decisions (as distinct from a decision made arbitrarily or capriciously), courts will generally not entertain objections to the debtor's conduct."). Although the determination of what constitutes a sufficient business reason depends on the facts and circumstances of each case, a debtor often satisfies the business judgment standard if the actions were undertaken "on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the company." *In re Integrated Res., Inc.*, 147 B.R. 650, 656 (Bankr. S.D.N.Y. 1992) (quoting *Smith v. Van Gorkom*, 488 A.2d 858, 872 (Del. 1985)). Moreover, "where the debtor articulates a reasonable basis for its business decisions (as distinct from a decision made arbitrarily or capriciously), courts will generally not entertain objections to the debtor's conduct." *In re Johns-Manville Corp.*, 60 B.R. at 616.

22. Additionally, section 105(a) of the Bankruptcy Code provides that the "court may issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of this title." 11 U.S.C. § 105(a). Pursuant to section 105(a), orders are appropriate where they are essential to the debtor's reorganization efforts and do not pose a burden on the debtor's creditors. *See U.S. Lines, Inc. v. Am. S.S. Owners Mut. Prof. & Indem. Ass'n (In re U.S. Lines, Inc.)*, 197 F.3d 631, 640 (2d Cir. 1999); *Momentum Mfg. Corp. v. Emp. Creditors Comm. (In re Momentum Mfg. Corp.)*, 25 F.3d 1132, 1136 (2d Cir. 1994) ("It is well settled that bankruptcy courts are courts of equity, empowered to invoke equitable principles to achieve fairness and justice in the reorganization process.").

23. The relief requested herein represents a sound exercise of the Debtors' judgment. As described above, the Debtors believe that continued development of the Product and HRT's

agreement to manufacture the Product at cost for the purpose of being donated or sold at cost will facilitate the pursuit of meaningful solutions to the opioid crisis through the development of advanced life-saving treatment options to prevent and reverse the effects of opioid overdose to the benefit of all stakeholders. The Debtors believe that the Product represents an important step toward increasing accessibility of overdose reversal medications and reducing cost, both of which are critical to combat the opioid crisis. The Debtors respectfully submit that the relief requested herein is based on the Debtors' sound business justification, is essential and appropriate, is in the best interests of their estates, creditors and the American public, and should be granted in all respects.

Debtors' Reservation of Rights

24. Nothing contained herein or any action taken pursuant to such relief is intended or shall be construed as (a) an admission as to the validity or priority of any claim against the Debtors; (b) a waiver of the Debtors' or any appropriate party in interest's rights to dispute the amount of, basis for or validity of any claim against the Debtors; (c) a waiver of any claims or causes of action which may exist against any creditor or interest holder or any other party; or (d) an approval, assumption, adoption or rejection of any agreement, contract, lease, program or policy between the Debtors and any third party under section 365 of the Bankruptcy Code. Likewise, if the Court grants the relief sought herein, any payment made pursuant to the Court's order is not intended to be and should not be construed as an admission as to the validity or priority of any claim or a waiver of the Debtors' rights to subsequently dispute such claim.

Waiver of Stay Under Bankruptcy Rule 6004(h)

25. The Debtors also request that, to the extent applicable to the relief requested in this Motion, the Court waive the stay imposed by Bankruptcy Rule 6004(h), which provides that "[a]n order authorizing the use, sale, or lease of property other than cash collateral is stayed until

the expiration of 14 days after entry of the order, unless the court orders otherwise." Fed. R. Bankr. P. 6004(h). As described above, the relief that the Debtors seek in this Motion is necessary for the Debtors to maximize the value of their estates. Accordingly, the Debtors respectfully request that the Court waive the 14-day stay imposed by Bankruptcy Rule 6004(h), as the nature of the relief sought herein justifies immediate relief.

Notice

26. Notice of this Motion will be provided as to (a) the entities on the Master Service List (as defined in the *Second Amended Order Establishing Certain Notice, Case Management, and Administrative Procedures* entered on November 18, 2019 [ECF No. 498] and available on the Debtors' case website at https://restructuring.primeclerk.com/purduepharma) and (b) any person or entity with a particularized interest in the subject matter of this motion (the "**Notice Parties**"). The Debtors respectfully submit that no further notice is required.

No Prior Request

27. The Debtors have not previously sought the relief requested herein from the Court or any other court.

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WHEREFORE, the Debtors respectfully request that the Court enter the proposed form of order, substantially in the form attached hereto, granting the relief requested herein and such other relief as the Court deems appropriate under the circumstances.

Dated: April 1, 2020
New York, New York

DAVIS POLK & WARDWELL LLP

By: */s/ Eli J. Vonnegut*

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